characterized, and one-of-a-kind artifacts. Proficiency testing may use *intralaboratory* techniques such as comparisons of computer software implementations to reference implementations, use of standard reference materials, and use of fundamental physical laws. Proficiency testing for calibration laboratories may involve the comparison of calibration results obtained independently by the laboratory and NIST/NVLAP on a selected instrument or artifact.

Proficiency testing data are analyzed by NVLAP and reports of the results are made known to the participants. Summary results are available upon request to other interested parties; e.g., professional societies and standards writing bodies. The identity and performance of individual laboratories are kept confidential.

Unsatisfactory participation in any NVLAP proficiency testing program is a technical deficiency which must be resolved in order to obtain initial accreditation or maintain accreditation.

Proficiency testing deficiencies are defined as, but not limited to, one or more of the following:

(i) failure to meet specified proficiency testing performance requirements prescribed by NVLAP;

(ii) failure to participate in a regularly scheduled "round" of proficiency testing for which the laboratory has received instructions and/or materials;

(iii) failure to submit laboratory control data as required;

(iv) performance as a statistically outlying laboratory in two successive rounds of proficiency testing or showing a general pattern of outlying results over three or more rounds; and

(v) failure to produce acceptable calibration or test results when using NIST Standard Reference Materials or special artifacts whose properties are well-characterized and known to NIST/NVLAP.

NVLAP will notify the laboratory of proficiency testing deficiencies and actions to be taken to resolve the deficiencies. Denial or suspension of accreditation will result from failure to resolve deficiencies.

(5) Technical Evaluation

A review panel is formed to determine if all technical requirements have been fulfilled. Each panel is composed of one or more NVLAP Technical Experts (evaluators) who are matched to the type of calibration or testing being evaluated and are selected to avoid conflict of interest. The evaluation is based on a review of the record of the laboratory as a whole, including:

(i) information provided on the application;

(ii) results of quality system documentation review;

(iii) on-site assessment reports;

(iv) actions taken by the laboratory to correct deficiencies;

(v) results of proficiency testing; and

(vi) information from any monitoring visits of the laboratory.

Based on this evaluation, the panel recommends whether or not a laboratory should be accredited. If the technical evaluation reveals additional deficiencies, written notification of the deficiencies will be made to the laboratory. The laboratory must respond as specified in the previous section, *Deficiency Notification and Resolution*.

All deficiencies must be resolved before accreditation can be granted.

(6) Monitoring Visits

In addition to regularly scheduled assessments, monitoring visits may be conducted by assessors or by NIST staff at any time during the accreditation period. They may occur for cause or on a random selection basis. While most monitoring visits will be scheduled in advance with the laboratory, NVLAP may conduct unannounced monitoring visits.

The scope of a monitoring visit may range from checking a few designated items to a complete review. The assessors may review deficiency resolutions, verify reported changes in the laboratory's personnel, facilities, or operations, or assist in resolving problems related to proficiency testing and other laboratory operations.

(c) NVLAP shall inform each applicant laboratory of any additional action(s) that the laboratory must take to qualify for accreditation.

Sec. 285.23 Granting and renewing accreditation

Accreditation is granted for a specified period, usually one year. Initial accreditation is granted when a laboratory has met all NVLAP requirements. One of four renewal dates is assigned (January 1, April 1, July 1, or October 1) and is usually retained as long as the laboratory remains in the program.

Renewal dates may be reassigned to provide benefits to the laboratory and/or NVLAP. If a renewal date is changed, the laboratory will be notified in writing of the change and any related adjustment in fees.

(a) NVLAP will take action to (1) grant initial accreditation, or (2) renew, suspend, or propose to deny or revoke accreditation of an applicant laboratory, based on the degree to which the laboratory complies with the specific NVLAP requirements.

(b) If accreditation is granted or renewed, NVLAP shall:

(1) provide a Certificate of Accreditation and a Scope of Accreditation to the laboratory;

(2) provide guidance on referencing the laboratory's accredited status, and the use of the NVLAP logo by the laboratory and its clients, as needed; and

(3) remind the laboratory that accreditation does not relieve it from complying with applicable federal, state, and local laws and regulations.

(c) NVLAP shall notify an accredited laboratory at least 30 days before its accreditation expires advising of the action(s) the laboratory must take to renew its accreditation.

Each accredited laboratory will be sent a renewal application package before the expiration date of its accreditation to allow sufficient time to complete the renewal process. Fees for renewal are charged according to services required as listed on the NVLAP Fee Schedule.

The application and fees must be received by NIST prior to expiration of the laboratory's current accreditation to avoid a lapse in accreditation.

Sec. 285.24 Denying, suspending, and revoking accreditation

(a) If NVLAP proposes to deny or revoke accreditation of a laboratory, NVLAP shall inform the laboratory of the reasons for the proposed denial or revocation and the procedure for appealing such a decision.

(b) The laboratory will have 30 days from the date of receipt of the proposed denial or revocation letter to appeal the decision to the Director of NIST. If the laboratory appeals the decision to the Director of NIST, the proposed denial or revocation will be stayed pending the outcome of the appeal. The proposed denial or revocation will become final through the issuance of a written decision to the laboratory in the event that the laboratory does not appeal the proposed denial or revocation within the 30-day period.

(c) If NVLAP finds that an accredited laboratory has violated the terms of its accreditation or the provisions of these procedures, NVLAP may, after consultation with the laboratory, suspend the

laboratory's accreditation, or advise of NVLAP's intent to revoke accreditation. If accreditation is suspended, NVLAP shall notify the laboratory of that action stating the reasons for and conditions of the suspension and specifying the action(s) the laboratory must take to have its accreditation reinstated.

If accreditation is revoked, the laboratory may be given the option of voluntarily terminating the accreditation.

(d) A laboratory whose accreditation has been denied, revoked, terminated, or expired, or which has withdrawn its application before being accredited, may reapply and be accredited if the laboratory:

(1) completes the assessment and evaluation process; and

(2) meets the conditions and criteria for accreditation that are set out in Sections 285.32 and 285.33.

(e) Conditions of suspension will include prohibiting the laboratory from using the NVLAP logo on its test or calibration reports during the suspension period. The determination of NVLAP whether to suspend or to propose revocation of a laboratory's accreditation will depend on the nature of the violation(s) of the terms of its accreditation.

If accreditation is revoked, the laboratory must return its Certificate of Accreditation and cease use of the NVLAP logo on any of its reports, correspondence, or advertising.

Sec. 285.25 Voluntary termination of accreditation

A laboratory may at any time terminate its participation and responsibilities as an accredited laboratory by advising NVLAP in writing of its desire to do so. NVLAP will terminate the laboratory's accreditation and notify the laboratory that its accreditation has been terminated in response to its request.

Sec. 285.26 Change in status of laboratory

Accreditation of a laboratory is based on specific conditions and criteria, including the laboratory ownership, location, staffing, facilities, and configuration. Changes in any of these conditions or criteria could result in loss of accreditation. NVLAP must be informed if any of the conditions or criteria for accreditation are changed so that a determination can be made concerning the status of the accreditation (see Section 285.32(a)(11)).

SUBPART D - CONDITIONS AND CRITERIA FOR ACCREDITATION

Sec. 285.31 Application of accreditation conditions and criteria

To become accredited and maintain accreditation, a laboratory must meet the conditions for accreditation set out in Section 285.32, the criteria set out in Section 285.33, and the guidance provided in the Handbooks for specific LAPs.

Sec. 285.32 Conditions for accreditation

(a) To become accredited and maintain accreditation, a laboratory shall agree in writing to:

(1) be assessed and evaluated initially and on a periodic basis;

(2) demonstrate, on request, that it is able to perform the calibrations or tests representative of those for which it is seeking accreditation;

(3) pay all fees;

(4) participate in proficiency testing as required;

(5) be capable of performing the calibrations or tests for which it is accredited according to the latest version of the calibration or test method within one year after its publication or within another time limit specified by NVLAP;

(6) limit the representation of the scope of its accreditation to only those calibrations, tests or services for which accreditation is granted;

(7) resolve all deficiencies;

(8) limit all its work or services for clients to those areas where competence and capacity are available;

(9) maintain records of all actions taken in response to complaints for a minimum of one year;

(10) maintain an independent decisional relationship between itself and its clients, affiliates, or other organizations so that the laboratory's capacity to render calibration or test reports objectively and without bias is not adversely affected;

(11) report to NVLAP within 30 days any major changes involving the location, ownership, management structure, Authorized Representative, Approved Signatories, or facilities of the laboratory; and

NOTE: In addition, a laboratory shall report to NVLAP within 30 days any major changes involving the following: deletion of a calibration parameter, test method or testing service for which it is accredited; or inability to perform calibrations, test methods or services for which it is accredited.

(12) return to NVLAP the Certificate of Accreditation and the Scope of Accreditation for revision or other action should it:

(i) be requested to do so by NVLAP;

(ii) voluntarily terminate its accredited status; or

(iii) become unable to conform to any of these conditions, the applicable criteria of Section 285.33, and related technical requirements.

(b) To become accredited and maintain accreditation, a laboratory shall supply, upon request, the following information to NVLAP or its designated contractor:

(1) legal name and full address;

(2) ownership of the laboratory;

(3) organization chart defining relationships that are relevant to performing testing and calibrations covered in the accreditation request;

(4) general description of the laboratory, including its facilities and scope of operation;

(5) name, address, and telephone and FAX number of the Authorized Representative of the laboratory;

(6) names or titles and qualifications of laboratory staff nominated to serve as approved signatories of calibration or test reports that reference NVLAP accreditation;

(7) the laboratory quality manual; and

(8) other information as may be needed for the specific LAP(s) in which accreditation is sought.

Sec. 285.33 Criteria for accreditation

(a) Scope

(1) This section sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific calibrations or tests.

(2) Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria, may be specified by NVLAP, depending upon the specific character of the task of the laboratory.

(3) This section is for use by calibration and testing laboratories in the development and implementation of their quality systems. It may also be used by accreditation bodies, certification bodies and others concerned with the competence of laboratories.

(4) A General Operations Checklist is used to verify compliance with the criteria of this section.

(b) Organization and management

(1) The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet these requirements.

(2) The laboratory shall:

(i) have managerial staff with the authority and resources needed to discharge their duties;

(ii) have policies to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

(iii) be organized in such a way that confidence in its independence of judgement and integrity is maintained at all times;

(iv) specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

(v) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

(vi) have a technical manager (however named) who has overall responsibility for the technical operations;

(vii) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

(viii) nominate deputies in case of absence of the technical or quality manager;

(ix) have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;

NOTE: It is recognized that this is not always a requirement for a laboratory. Where confidentiality and protection of proprietary rights are required by the customer, the laboratory policies and procedures shall be documented in the quality manual.

(x) where appropriate, participate in interlaboratory comparisons and proficiency testing programs;

(xi) have documented policy and procedures to ensure that its clients are served with impartiality and integrity.

(c) Quality system, audit and review

(1) The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration and testing activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manager.

(2) The quality manual, and related documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of these procedures. The quality manual and related quality documentation shall also contain:

(i) a quality policy statement, including objectives and commitments, by top management;

(ii) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

(iii) the relations between management, technical operations, support services and the quality system;

(iv) procedures for control and maintenance of documentation;

(v) job descriptions of key staff and reference to the job descriptions of other staff;

(vi) identification of the laboratory's approved signatories;

(vii) the laboratory's procedures for achieving traceability of measurements;

(viii) the laboratory's scope of calibrations and/or tests;

(ix) arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

(x) reference to the calibration, verification and/or test procedures used;

(xi) procedures for handling calibration and test items;

(xii) reference to the major equipment and reference measurement standards used;

(xiii) reference to procedures for calibration, verification and maintenance of equipment;

(xiv) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;

(xv) procedures to be followed for feedback and corrective action whenever discrepancies are detected, or departures from documented policies and procedures occur;

(xvi) the laboratory management policies for departures from documented policies and procedures or from standard specifications;

(xvii) procedures for dealing with complaints;

(xviii) procedures for protecting confidentiality and proprietary rights;

(xix) procedures for audit and review;

(xx) a description of the laboratory's policy regarding the use of the NVLAP logo;

(xxi) a statement of the laboratory's policy for establishing and changing calibration intervals for equipment it controls; and

(xxii) a statement of the laboratory's policy concerning the technique(s) to be used for determining measurement uncertainty and calibration/verification adequacy.

(3) The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. When the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

The audits shall be objective and be conducted internally or on contract. The audits shall include both general criteria (documents, records and policies) and technical compliance (test methods and practices and calibration procedures).

(4) The quality system adopted to satisfy the requirements of this section shall be reviewed at least once each year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

(5) All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

(6) In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

(i) internal quality control plans using whenever possible statistical techniques;

NOTE: Measurement assurance techniques are acceptable means to control the measurement process and consistently produce the highest quality measurements.

(ii) participation in proficiency testing or other interlaboratory comparisons;

(iii) regular use of certified reference materials and/or in-house quality control using secondary reference materials;

(iv) replicate testings using the same or different methods;

(v) retesting of retained items;

(vi) correlation of results for different characteristics of an item.

(d) Personnel

(1) The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

(2) The laboratory shall ensure that the training of its personnel is kept up-to-date.

(3) Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

(e) Accommodation and environment

(1) Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

NOTE: Laboratory design will be, to the maximum extent practical, in accordance with the guidelines found in the NCSL Recommended Practice #7, *Laboratory Design*, July 25, 1993.

(2) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

NOTE: It is expected that environments which do not meet generally accepted norms, such as those found in NCSL Recommended Practice #7, yet which exhibit the stability required to apply necessary correction factors, will be specified by the laboratory for the purpose of assessment of compliance with its own procedures to achieve its stated uncertainties.

(3) The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

(4) There shall be effective separation between neighboring areas when the activities therein are incompatible.

(5) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

(6) Adequate measures shall be taken to ensure good housekeeping in the laboratory.

NOTE: It is the laboratory's responsibility to comply with relevant health, safety and environmental requirements. This aspect, however, is outside the scope of this handbook.

(f) Equipment and reference materials

(1) The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this section are met.

(2) All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

(3) Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.

(4) Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include:

(i) the name of the item of equipment;

(ii) the manufacturer's name, type identification, and serial number or other unique identification;

(iii) date received and date placed in service;

NOTE: For initial accreditation, the date received and the date placed in service are not considered mandatory requirements for inclusion in laboratory records, although this is encouraged as good laboratory practice.

(iv) current location, where appropriate;

(v) condition when received (e.g., new, used, reconditioned);

(vi) copy of the manufacturer's instructions, where available;

(vii) dates and results of calibrations and/or verifications and date of next calibration and/or verification;

(viii) details of maintenance carried out to date and planned for the future;

(ix) history of any damage, malfunction, modification or repair; and

(x) measured value observed for each parameter found to be out of tolerance during calibration/verification.

(g) Measurement traceability and calibration

(1) All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. The program will ensure the recall or removal from service of any standard or equipment which has exceeded its calibration interval or is otherwise judged to be unreliable.

(2) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall, wherever available, indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

NOTE: Traceability to national standards includes traceability to standards maintained or defined at national laboratories in foreign countries where applicable. In these cases, traceability is achieved via international standards. This includes intrinsic standards of measurement where available.

Where applicable, the methodology of the *Guide to the expression of uncertainty in measurement*: 1993, shall be used as the basis for expression of uncertainty of the measurement. NIST Technical Note 1297; January 1993, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results*, is a practical application document written around the *Guide to the expression of uncertainty in measurement*. Where detailed procedures are not used to quantify and combine uncertainties (i.e., use of test accuracy ratio concepts), the sources of uncertainty shall be tabulated and demonstrated to be acceptable for the measurement undertaken.

NOTE: A significant number of intrinsic standards, such as the Josephson Array Voltage Standard and the Iodine-Stabilized Helium-Neon Laser Length Standard, have been developed and are now being used by many national standards laboratories and some industrial laboratories. These standards are based on well-characterized laws of physics, fundamental constants of nature, or invariant properties of materials, and make ideal stable, precise, and accurate measurement standards if properly designed, characterized, operated, monitored and maintained. Where intrinsic standards are used, the laboratory should demonstrate by measurement assurance techniques, interlaboratory comparisons, or other suitable means, that its intrinsic standard measurement results are correlated with those of national or international standards.

(3) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons or proficiency testing.

NOTE: Traceability requirements may also be satisfied by:

(i) internationally accepted standards in the field concerned;

(ii) suitable reference materials;

(iii) ratio or reciprocity measurements; or

(iv) mutual consent standards which are clearly specified and mutually agreed upon by all parties concerned.

(4) Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

(5) Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a program of calibration and verification for reference standards.

(6) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

(7) Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

(h) Calibration and test methods

(1) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

(2) The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

NOTES:

(i) Calibration procedures shall contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified. In addition, the procedures shall contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards. The procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations/verifications concerned.

(ii) The laboratory shall ensure that the calibration uncertainties are sufficiently small so that the adequacy of the measurement is not affected. Well-defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of a measurement process. If such techniques are not used, then the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the measuring and test equipment being calibrated or verified.

(3) Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

(4) Where it is necessary to employ methods that have not been established as standard, this shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.

(5) Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

(6) Calculations and data transfers shall be subject to appropriate checks.

(7) Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall ensure that:

(i) the requirements of these procedures are complied with;

(ii) computer software is documented and adequate for use;

(iii) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

(iv) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data;

(v) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

(8) Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

(i) **Handling of calibration and test items**

(1) The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time.

(2) Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

(3) The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

(4) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

(5) Tamper-resistant seals shall be affixed to operator-accessible controls or adjustments on measurement standards or measuring and test equipment which, if moved, will invalidate the calibration. The laboratory's calibration system shall provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals.

NOTE: Tamper-resistant seals are sometimes affixed to equipment to prevent unauthorized access to areas where adjustments or critical components are located.

(j) **Records**

(1) The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

EXCEPTION: The retention of all original observations, calculations, and derived data in the calibration record system is not a mandatory requirement for calibration laboratories, although it is encouraged as good laboratory practice.

(2) All records (including those listed in 285.33(f)(4) pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client.

NOTE: The period of retention shall be specified in the quality manual.

(k) Certificates and reports

(1) The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used.

NOTE: It is recognized that the results of each calibration do not always result in the production of a calibration certificate or report. Whenever a certificate or report is produced, the above requirements shall be met.

(2) Each certificate or report shall include at least the following information:

(i) a title, e.g., "Calibration Certificate", "Test Report" or "Test Certificate";

(ii) name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;

(iii) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

(iv) name and address of client, where appropriate;

(v) description and unambiguous identification of the item calibrated or tested;

(vi) characterization and condition of the calibration or test item;

(vii) date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;

EXCEPTION: Although it is encouraged as good laboratory practice, the requirement for inclusion of the date received is not mandatory for calibration laboratories.

(viii) identification of the calibration or test method used, or unambiguous description of any non-standard method used;

(ix) reference to sampling procedure, where relevant;

(x) any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific calibration or test, such as environmental conditions;

(xi) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;

(xii) a statement of the estimated uncertainty of the calibration or test result (where relevant);

(xiii) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

(xiv) where relevant, a statement to the effect that the results relate only to the items calibrated or tested;

(xv) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory;

(xvi) a statement that the report must not be used by the client to claim product endorsement by NVLAP or any agency of the U.S. Government;

(xvii) the signature of an Approved Signatory for all test and calibration reports endorsed with the NVLAP logo;

(xviii) special limitations of use; and

(xix) traceability statement.

(3) Where the certificate or report contains results of calibrations or tests performed by subcontractors, these results shall be clearly identified.

(4) Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible.

(5) Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate (or Test Report or Test Certificate), serial number... [or as otherwise identified]," or equivalent form of wording. Such amendments shall meet all the relevant requirements of 285.33(j).

(6) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.

NOTE: Such notification shall quantify the magnitude of error created in the calibration results. The laboratory shall notify customers promptly, in writing, of any customer's measuring and test equipment found significantly out of tolerance during the calibration/verification process. Measurement data shall be reported so that appropriate action can be taken.

(7) The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of these procedures are met and that confidentiality is preserved.

(8) Whenever a laboratory accredited by NVLAP issues a calibration or test report which contains data covered by the accreditation and also data not covered by the accreditation, it must clearly identify in its records, and in the report to the client, specifically which calibration or test method(s), or portion of a calibration or test method(s), was not covered by the accreditation. The laboratory must also inform the client, before the fact, when calibrations or tests requested are not covered by the accreditation.

NVLAP policy regarding calibration and test reports issued by an accredited laboratory, which reference the laboratory's accredited status, requires that any calibration or test report containing data from calibrations or tests which are not covered by the accreditation include:

(i) a statement at the beginning of the report prominently indicating, "This report contains data which are not covered by the NVLAP accreditation"; and

(ii) a clear indication of which data are not covered by the accreditation.

The laboratory must not misrepresent its accreditation. When a client requires or requests accredited services and any of the requested services are not covered by the

accreditation, the client must be so advised.

(l) Subcontracting of calibration or testing

(1) Where a laboratory subcontracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being subcontracted. The laboratory shall advise the client in writing of its intention to subcontract any portion of the calibration or testing to another party.

(2) The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain a register of all subcontracting.

(3) A NVLAP-accredited laboratory intending to subcontract testing or calibration work that will be performed and reported as meeting NVLAP procedures and criteria must:

(i) have in its quality manual a subcontracting policy compatible with the NVLAP policy, with a description of the procedures for administering and implementing those actions to demonstrate the conformance and consistency of the subcontracted laboratory to perform according to NVLAP procedures;

(ii) place the subcontracted work with a laboratory that maintains accreditation established by NVLAP shown by a current NVLAP Lab Code, or provide and maintain current records that demonstrate that the subcontracted laboratory is competent to perform the test(s) or calibration(s), and that it operates in a manner consistent with and in conformance to NVLAP criteria for accreditation;

(iii) clearly identify in its records, and in the report to the client, exactly which data were obtained by the NVLAP-accredited laboratory and which data were obtained by the subcontractor, NVLAP-accredited or not;

(iv) inform its client, before the fact, that it intends to subcontract for completion of all or a portion of the client's work; and

(v) include at the beginning of the report the name, address, and contact person of the subcontracted laboratory(ies), and one of the following statements, as appropriate:

if NVLAP-accredited,

"This report contains data which were produced by a subcontracted laboratory **ACCREDITED (NVLAP LAB CODE)** for the calibration or test methods performed."

if not NVLAP-accredited,

"This report contains data which were produced by a subcontracted laboratory **NOT ACCREDITED** for the calibration or test methods performed."

The requirements of this section do not supersede any regulation, law, contract specification, or other related conditions which require NVLAP accreditation.

(m) Outside support services and supplies

(1) Where the laboratory procures outside services and supplies in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

(2) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and

consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

(3) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

(n) Complaints

(1) The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

(2) Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this section or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with Section 285.33(c)(3).

NOTE: This is interpreted to mean that complaints in those areas of activity and responsibility involved must be promptly resolved.

(o) Measuring and test equipment (M & TE)

NOTE: This section applies to the control of measuring and test equipment (M & TE) used to assure that supplies and services comply with prescribed customer requirements. It is based in large part on the requirements found in government audit standards such as MIL-STD 45662A, and is found in Part II of the ANSI/NCSL Z540-1-1994 (Draft) standard.

(1) General requirements for M & TE

(i) The supplier shall establish and document a system to control the calibration/verification of M & TE.

(ii) M & TE used to determine compliance with customer technical specifications shall be calibrated or verified in accordance with 285.33(b) through (n) of this handbook.

(iii) The supplier shall have a program to recall for calibration or verification, or remove from service, M & TE that has exceeded its calibration interval, has broken calibration seals, or is suspected to be malfunctioning due to mishandling, misuse, or unusual results.

(iv) All operations performed by the supplier in compliance with this handbook shall be subject to customer verification at unscheduled intervals.

(v) The supplier shall carry out, or arrange to have carried out, periodic quality auditing of the calibration and verification system in order to ensure its continuing effective implementation and compliance with the requirements of this handbook.

- Based on the results of the audits and any other relevant factors, such as customer feedback, the supplier shall review and modify the system as necessary.

- Plans and procedures for the audits shall be documented. The conduct of the audit and any subsequent corrective action shall also be documented.

(2) Detailed requirements for M & TE

(i) Calibration system description: The supplier shall provide and maintain a written description of the calibration/verification system covering M & TE and measurement standards. The description shall be sufficient to satisfy each requirement of 285.33(o) of this handbook and any deviations shall be submitted with supporting documentation to the customer for approval.

(ii) Adequacy of measurement standards: Measurement standards used by the supplier for calibrating M & TE and other measurement standards shall comply with the requirements of 285.33(f)(1), 285.33(g)(1), and 285.33(h)(2) of this handbook.

(iii) Environmental conditions: M & TE shall be used in an environment controlled to the extent necessary to ensure valid results. Due consideration shall be given to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference and any other factors affecting the results of measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.

(iv) Intervals of calibration and verification: M & TE requiring calibration shall be calibrated or verified at periodic intervals established and maintained to assure acceptable reliability, where reliability is defined as the probability that M & TE will remain in-tolerance throughout the interval. Intervals shall be established for all M & TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards must closely represent the item parameters normally tested in the process and the check standard must be verified periodically. Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained. Intervals may be based on usage or time since last calibration or verification. All exemptions from periodic calibration or verification shall be documented. The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of the customer's requirements.

(v) Calibration procedures: Procedures used to calibrate/verify the supplier's M & TE shall comply with the requirements of 285.33(h)(1) and 285.33(h)(2) of this handbook.

(vi) Out-of-tolerance conditions: If any M & TE is found to be significantly out of tolerance during the calibration/verification process, the supplier's system shall provide for notification to the user and to the supplier's quality element, if appropriate, of the out-of-tolerance condition with the associated measurement data so that appropriate action can be taken.

(vii) Adequacy of calibration system: The supplier shall establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with the requirements of this handbook.

(viii) Calibration sources: M & TE requiring calibration shall be calibrated or verified by laboratories that comply with sections 285.33(b) through (n) of this handbook.

(ix) Records: The requirements of this handbook shall be supported by records documenting that established schedules and procedures are followed to maintain the adequacy of all M & TE. The records for M & TE requiring calibration shall include an individual record of calibration or verification, or other means of control, providing a description or identification of the item, calibration interval, date calibrated, identification of the calibration source, calibration results (data and/or condition status) and calibration action taken (adjusted, repaired, new value assigned, derated, etc.).

(x) Calibration status: M & TE shall be labeled to indicate calibration or verification status. The label shall identify specific date calibrated (day, month, year, Julian date, or equivalent) and the specific calibration due date or usage equivalent. Items not calibrated to their full capability or which have other limitations of use, shall be labeled or otherwise identified as to the limitations. When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status. Tamper-resistant seals are affixed to operator accessible controls or adjustments which if moved will invalidate the calibration. The quality system shall provide instructions for the disposition of equipment with broken tamper-resistant seals.

(xi) Control of subcontractor calibration: The supplier is responsible for assuring that the subcontractor's calibration system conforms to 285.33(l) of this handbook to the degree necessary to assure compliance with contractual requirements. NVLAP accreditation of the subcontractor's laboratory can serve as the basis for compliance with this requirement.

(xii) Storage and handling: M & TE shall be handled, stored, and transported in a manner which shall not adversely affect the calibration or condition of the equipment.

NIST-114 (REV. 6-93) ADMAN 4.09

U.S. DEPARTMENT OF COMMERCE
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

MANUSCRIPT REVIEW AND APPROVAL

(ERB USE ONLY)
ERB CONTROL NUMBER: W94-0644
DIVISION: 214
PUBLICATION REPORT NUMBER: NIST HB 150
CATEGORY CODE: 220

INSTRUCTIONS: ATTACH ORIGINAL OF THIS FORM TO ONE (1) COPY OF MANUSCRIPT AND SEND TO THE SECRETARY, APPROPRIATE EDITORIAL REVIEW BOARD

PUBLICATION DATE: March 1994
NUMBER PRINTED PAGES: 42

TITLE AND SUBTITLE (CITE IN FULL)

National Voluntary Laboratory Accreditation Program (NVLAP)
Procedures and General Requirements

CONTRACT OR GRANT NUMBER

TYPE OF REPORT AND/OR PERIOD COVERED

AUTHOR(S) (LAST NAME, FIRST INITIAL, SECOND INITIAL)

Cigler, J. L. and White, V. R., Editors

PERFORMING ORGANIZATION (CHECK (X) ONE BOX)
- [X] NIST/GAITHERSBURG
- [ ] NIST/BOULDER
- [ ] JILA/BOULDER

LABORATORY AND DIVISION NAMES (FIRST NIST AUTHOR ONLY)

Technology Services, Office of Standards Services, Laboratory Accreditation Program

SPONSORING ORGANIZATION NAME AND COMPLETE ADDRESS (STREET, CITY, STATE, ZIP)

NIST
Gaithersburg, MD 20899

PROPOSED FOR NIST PUBLICATION

- [ ] JOURNAL OF RESEARCH (NIST JRES)
- [ ] J. PHYS. & CHEM. REF. DATA (JPCRD)
- [X] HANDBOOK (NIST HB)
- [ ] SPECIAL PUBLICATION (NIST SP)
- [ ] TECHNICAL NOTE (NIST TN)
- [ ] MONOGRAPH (NIST MN)
- [ ] NATL. STD. REF. DATA SERIES (NIST NSRDS)
- [ ] FEDERAL INF. PROCESS. STDS. (NIST FIPS)
- [ ] LIST OF PUBLICATIONS (NIST LP)
- [ ] NIST INTERAGENCY/INTERNAL REPORT (NISTIR)
- [ ] LETTER CIRCULAR
- [ ] BUILDING SCIENCE SERIES
- [ ] PRODUCT STANDARDS
- [ ] OTHER

PROPOSED FOR NON-NIST PUBLICATION (CITE FULLY) [ ] U.S. [ ] FOREIGN

PUBLISHING MEDIUM
- [X] PAPER
- [ ] CD-ROM
- [ ] DISKETTE (SPECIFY)
- [ ] OTHER (SPECIFY)

SUPPLEMENTARY NOTES

ABSTRACT (A 2000-CHARACTER OR LESS FACTUAL SUMMARY OF MOST SIGNIFICANT INFORMATION. IF DOCUMENT INCLUDES A SIGNIFICANT BIBLIOGRAPHY OR LITERATURE SURVEY, CITE IT HERE. SPELL OUT ACRONYMS ON FIRST REFERENCE.) (CONTINUE ON SEPARATE PAGE, IF NECESSARY.)

NIST Handbook 150 presents the basic procedures and general accreditation requirements of NVLAP for use in accrediting calibration and testing laboratories. It is intended for information and use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, users of laboratory services, and others needing information on the requirements for accreditation under the National Voluntary Laboratory Accreditation Program (NVLAP).

This handbook contains Part 285 of Title 15 of the U.S. Code of Federal Regulations (CFR), "National Voluntary Laboratory Accreditation Program Procedures and General Requirements," plus all general procedures, criteria, and policies formerly contained in the individual NVLAP technical handbooks and separately published NVLAP policies. This organization of the material was adopted so that users of the handbook can readily access all general accreditation requirements for a given subject in one place. Subpart D, Sections 285.33(a) through (n), is essentially identical to the language of ISO Guide 25, "General requirements for the competence of calibration and testing laboratories," with additions as a result of NVLAP interpretation of ISO Guide 25 via ANSI/NCSL Z540-1-1994 (draft). Section 285.33(o) was added in its entirety as contained in ANSI/NCSL Z540-1-1994 (draft) for assessment of quality systems for the control of Measuring and Test Equipment (M & TE), and is based in large part on the requirements of MIL-STD-45662A.

KEY WORDS (MAXIMUM OF 9; 28 CHARACTERS AND SPACES EACH; SEPARATE WITH SEMICOLONS; ALPHABETIC ORDER; CAPITALIZE ONLY PROPER NAMES)
accreditation; calibration laboratory; laboratory; NVLAP; procedures; quality; requirements; testing laboratory

AVAILABILITY
- [X] UNLIMITED
- [ ] FOR OFFICIAL DISTRIBUTION - DO NOT RELEASE TO NTIS
- [X] ORDER FROM SUPERINTENDENT OF DOCUMENTS, U.S. GPO, WASHINGTON, DC 20402
- [X] ORDER FROM NTIS, SPRINGFIELD, VA 22161

NOTE TO AUTHOR(S): IF YOU DO NOT WISH THIS MANUSCRIPT ANNOUNCED BEFORE PUBLICATION, PLEASE CHECK HERE. [ ]

WORDPERFECT

NIST Technical Publications

Periodical

Journal of Research of the National Institute of Standards and Technology—Reports NIST research and development in those disciplines of the physical and engineering sciences in which the Institute is active. These include physics, chemistry, engineering, mathematics, and computer sciences. Papers cover a broad range of subjects, with major emphasis on measurement methodology and the basic technology underlying standardization. Also included from time to time are survey articles on topics closely related to the Institute's technical and scientific programs. Issued six times a year.

Nonperiodicals

Monographs—Major contributions to the technical literature on various subjects related to the Institute's scientific and technical activities.

Handbooks—Recommended codes of engineering and industrial practice (including safety codes) developed in cooperation with interested industries, professional organizations, and regulatory bodies.

Special Publications—Include proceedings of conferences sponsored by NIST, NIST annual reports, and other special publications appropriate to this grouping such as wall charts, pocket cards, and bibliographies.

Applied Mathematics Series—Mathematical tables, manuals, and studies of special interest to physicists, engineers, chemists, biologists, mathematicians, computer programmers, and others engaged in scientific and technical work.

National Standard Reference Data Series—Provides quantitative data on the physical and chemical properties of materials, compiled from the world's literature and critically evaluated. Developed under a worldwide program coordinated by NIST under the authority of the National Standard Data Act (Public Law 90-396). NOTE: The Journal of Physical and Chemical Reference Data (JPCRD) is published bimonthly for NIST by the American Chemical Society (ACS) and the American Institute of Physics (AIP). Subscriptions, reprints, and supplements are available from ACS, 1155 Sixteenth St., NW, Washington, DC 20056.

Building Science Series—Disseminates technical information developed at the Institute on building materials, components, systems, and whole structures. The series presents research results, test methods, and performance criteria related to the structural and environmental functions and the durability and safety characteristics of building elements and systems.

Technical Notes—Studies or reports which are complete in themselves but restrictive in their treatment of a subject. Analogous to monographs but not so comprehensive in scope or definitive in treatment of the subject area. Often serve as a vehicle for final reports of work performed at NIST under the sponsorship of other government agencies.

Voluntary Product Standards—Developed under procedures published by the Department of Commerce in Part 10, Title 15, of the Code of Federal Regulations. The standards establish nationally recognized requirements for products, and provide all concerned interests with a basis for common understanding of the characteristics of the products. NIST administers this program in support of the efforts of private-sector standardizing organizations.

Consumer Information Series—Practical information, based on NIST research and experience, covering areas of interest to the consumer. Easily understandable language and illustrations provide useful background knowledge for shopping in today's technological marketplace.

Order the **above** *NIST publications from: Superintendent of Documents, Government Printing Office, Washington, DC 20402.*

Order the **following** *NIST publications—FIPS and NISTIRs—from the National Technical Information Service, Springfield, VA 22161.*

Federal Information Processing Standards Publications (FIPS PUB)—Publications in this series collectively constitute the Federal Information Processing Standards Register. The Register serves as the official source of information in the Federal Government regarding standards issued by NIST pursuant to the Federal Property and Administrative Services Act of 1949 as amended, Public Law 89-306 (79 Stat. 1127), and as implemented by Executive Order 11717 (38 FR 12315, dated May 11, 1973) and Part 6 of Title 15 CFR (Code of Federal Regulations).

NIST Interagency Reports (NISTIR)—A special series of interim or final reports on work performed by NIST for outside sponsors (both government and non-government). In general, initial distribution is handled by the sponsor; public distribution is by the National Technical Information Service, Springfield, VA 22161, in paper copy or microfiche form.

U.S. DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
National Voluntary Laboratory Accreditation Program (NVLAP)
Building 411, Room A162
Gaithersburg, MD 20899

BULK RATE
POSTAGE & FEES PAID
NIST
PERMIT NO. G195

Official Business

Penalty for Private Use $300

FORWARDING AND RETURN POSTAGE GUARANTEED
ADDRESS CORRECTION REQUESTED

ET 95-19

NVLAP®

National Voluntary Laboratory Accreditation Program

General Application and Instructions

OMB Number: 0693-0003
Approval Expires: November 30, 1996

U.S. Department of Commerce
Technology Administration
National Institute of Standards and Technology

NIST

NVLAP®

National Voluntary Laboratory Accreditation Program

INSTRUCTIONS FOR COMPLETING AN APPLICATION FOR ACCREDITATION

(1) Thoroughly read all documents furnished in this application package in order to understand the NVLAP accreditation requirements.

(2) Print or type all requested information. Where more space is needed for responses, attach additional pages to the application and identify the question(s) being answered.

(3) Complete the attached **GENERAL APPLICATION**. The laboratory's Authorized Representative must sign page 4 of the General Application to signify agreement with the NVLAP Conditions for Accreditation.

(4) Complete a **PROGRAM-SPECIFIC APPLICATION** for each program in which you are applying for accreditation.

(5) Complete the appropriate **FEE CALCULATION WORKSHEETS**, using the NVLAP Fee Schedule, and remit the required fee with the application. Payment may be made by check, purchase order or charge card. An application will not be processed until payment is received.

(6) Make checks and purchase orders payable to: **NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY.** Print "NVLAP" and your NVLAP Lab Code (if assigned) on your check or purchase order to ensure that payment will be credited to the proper account.

To make payment by charge card, complete the **AUTHORIZATION TO CHARGE MASTERCARD OR VISA** that is included with the Fee Calculation Worksheet.

(7) Send all applications and worksheets (retain a photocopy for your records) with payment to:

National Institute of Standards and Technology
NVLAP/Accounts
Route 270 and Quince Orchard Road
Bldg. 101/Room A807
Gaithersburg, MD 20899.

For assistance or information, call NVLAP at (301) 975-4016 or FAX (301) 926-2884.

This application will not be processed until all questions (1 - 9) have been completed and the application has been signed.

NVLAP LAB CODE: [ ]

NVLAP GENERAL APPLICATION

(CFR Title 15, Part 285, Section 285.32(b))

1. **LEGAL NAME AND FULL ADDRESS** of the laboratory. This laboratory name and address will appear on the Certificate and Scope of Accreditation and in NVLAP directories, and will be used for all correspondence with the laboratory.

   Laboratory Name _____

   Street _____

   P. O. Box _____

   City _____ State _____ ZIP + 4 _____

   Country _____

2. Name and type of **OWNERSHIP** of the laboratory (e.g., stock company, sole proprietorship, partnership, etc.)

   _____

   Name of owner Type

3. Is the laboratory currently NVLAP-accredited for any field of testing or calibration?
   ____ yes ____ no. If yes, please identify its four-digit NVLAP Lab Code: _____.

4. Check one of the following as it applies to the laboratory:

   a. Testing laboratory

      ___ Commercial testing service
      ___ Sometimes available for commercial testing
      ___ Normally not available for commercial testing

   b. Calibration laboratory

      ___ Government
      ___ Non-government

5. **AUTHORIZED REPRESENTATIVE** of the laboratory. The Authorized Representative is responsible for ensuring that the laboratory complies with the conditions and criteria for accreditation. This person's name will appear in NVLAP directories and on Scopes of Accreditation. The Authorized Representative will receive all NVLAP correspondence, receive proficiency testing materials and reports, and be contacted about on-site assessments.

Printed Name	Title	Phone Number	FAX Number

6. **APPROVED SIGNATORY(S)** of the laboratory. An Approved Signatory is recognized by NVLAP as competent to sign accredited laboratory calibration or test reports. The laboratory must designate one or more staff members as an Approved Signatory. The laboratory's Authorized Representative may, if appropriate, also serve as an Approved Signatory. (If more space is needed, attach additional pages.)

Printed Name	Title	Phone Number
Printed Name	Title	Phone Number

7. To become accredited and maintain accreditation, the testing or calibration laboratory must supply, upon request, its **QUALITY MANUAL** to NVLAP or its designated contractor. Call NVLAP for specific instructions regarding the laboratory's Quality Manual for laboratory accreditation program(s) covered by this application.

8. Attach a detailed organizational chart of the laboratory that shows name and position title for all key personnel.

   If applicable, provide an organizational chart showing the relationship of the laboratory to other corporate entities (e.g., design, production, marketing, quality or other operating units). Individual names and titles are not required for this chart. In order for NVLAP to assess the independent decisional relationship of the laboratory with other parts of the organization, the chart must show the reporting path of the laboratory director to the next level of management.

9. Attach a description of the laboratory and laboratory facilities as it applies to the NVLAP accreditation activities. The description should include laboratory purpose, laboratory size and layout, staff size, major equipment, and use of remote sites/sub-facilities/mobile-units.

   Describe the scope of operation of the laboratory in the fields of testing or calibration for which accreditation is being sought, including an indication of the amount of testing or calibration that is performed. Note that additional information may be requested in the program-specific applications.

   Include a brief overview of other testing or calibration services offered by this laboratory.

NVLAP LAB CODE:

CONDITIONS FOR ACCREDITATION

(CFR Title 15, Part 285, Section 285.32(a))

In order to become accredited and maintain accreditation, a laboratory shall agree in writing to:

(1) be assessed and evaluated initially and on a periodic basis;

(2) demonstrate, on request, that it is able to perform the calibrations or tests representative of those for which it is seeking accreditation;

(3) pay all fees;

(4) participate in proficiency testing as required;

(5) be capable of performing the calibrations or tests for which it is accredited according to the latest version of the calibration or test method within one year after its publication or within another time limit specified by NVLAP;

(6) limit the representation of the scope of its accreditation to only those calibrations, tests or services for which accreditation is granted;

(7) resolve all deficiencies;

(8) limit all its work or services for clients to those areas where competence and capacity are available;

(9) maintain records of all actions taken in response to complaints for a minimum of one year;

(10) maintain an independent decisional relationship between itself and its clients, affiliates, or other organizations so that the laboratory's capacity to render calibration or test reports objectively and without bias is not adversely affected;

(11) report to NVLAP within 30 days any major changes involving the location, ownership, management structure, Authorized Representative, Approved Signatories, or facilities of the laboratory; and

(12) return to NVLAP the Certificate of Accreditation and the Scope of Accreditation for revision or other action should it: (i) be requested to do so by NVLAP; (ii) voluntarily terminate its accredited status; or (iii) become unable to conform to any of these conditions, the applicable criteria of Section 285.33, and related technical requirements.

As the applicant laboratory's **Authorized Representative**, I agree to the above conditions for accreditation. I attest that all statements made in this application are correct to the best of my knowledge and are made in good faith.

Signature _____ Date _____